K003811

OCT 1 1 2001

Section II - Summary of Safety and Effectiveness

(1) Contact Information

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(2) Company Information

Endocare, Inc.
7 Studebaker
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Telephone: (949) 595-4770
FAX: (949) 595-4766

(3) Device Name

Cryocare® Surgical System

(4) Device Description

The Cryocare™ Surgical System consists of a control unit that controls one to eight single-use, disposable CryoProbes. The control unit is software-controlled and operates off standard 110/230 VAC wall power. A 486 IBM-compatible microprocessor serves as the host computer and a screen displays the status of the system. System control is accomplished either directly through keys on the console itself (e.g., 1-probe system) or through a remote control keypad (e.g., 4 and 8-probe system). The CryoProbes operate on the Joule-Thompson principle and the refrigerative capacity is limited only to the distal tip of the probe. The CryoProbes incorporate a thermocouple to measure temperatures at the probe tip. The thermocouple is mounted inside each CryoProbe tip and its signal is used to monitor and control some operations of the system. The control unit can also control one to eight independent TempProbes™ to monitor temperatures in surrounding tissues. The temperature probes are standard T-type needle thermocouples.

The system utilizes inert argon gas as a cooling agent. The system is available in 1, 4 and 8-CryoProbe configurations. The performance characteristics and internal design of each model are equivalent. The primary differences are the number of valves to control the CryoProbes (e.g., 1-8), number of thermocouple inputs (e.g., 1-8) and the size of the outer case. No design changes have been made to the system as a result of the additional indication for use.

(5) Indications for Use

The Cryocare® Surgical System is intended for use in general surgery, urology, gynecology, oncology, neurology, thoracic surgery, dermatology, ENT, and proctology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate, kidney and breast fibroadenoma tissue, liver metastases, tumors, skin lesions, and warts. In addition, the system is intended for use in the following indications:

Urology

- Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia

Oncology

- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

Dermatology

- Ablation or freezing of skin cancers and other cutaneous disorders

Gynecology

- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

General Surgery

- Destruction of warts or lesions
- Palliation of tumors of the oral cavity, rectum and skin
- Ablation of breast fibroadenoma
- Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemanglomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, recurrent cancerous lesions

Thoracic Surgery

- Ablation of arrhythmic cardiac tissue
- Ablation of cancerous lesions

Proctology

- Ablation of benign or malignant growths of the anus or rectum
- Ablation of hemorrhoids

(6) Name of Predicate or Legally Marketed Device

Cryocare® Surgical System

(7) Substantial Equivalence

The Cryocare® Surgical System for the ablation of breast fibroadenoma is substantially equivalent to the Cryocare® Surgical System that was determined to be substantially equivalent on December 22, 1997 (reference K9783686) and April 10, 1998 (reference K980110).

(8) Performance Data Summary

Clinical testing demonstrated that the use the Cryocare® Surgical System for the ablation of breast fibroadenoma tissue is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2001

Mr. Vincent Cutarelli
Senior Vice President, Regulatory Affairs
and Quality Assurance
Endocare, Inc.
7 Studebaker
Irvine, California 92618

Re: K003811
Trade/Device Name: Cryocare™ Surgical System
Regulation Number: 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: July 12, 2001
Received: July 16, 2001

Dear Mr. Cutarelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number: K003811

Device Name: Cryocare™ Surgical System

Indications for Use: The Cryocare® Surgical System is intended for use in general surgery, urology, gynecology, oncology, neurology, thoracic surgery, dermatology, ENT, and proctology. The system is designed to destroy tissue by the application of extreme cold temperatures including prostate, kidney, breast fibroadenoma tissue, liver metastases, tumors, skin lesions, and warts. In addition, the system is intended for use in the following indications:

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Dermatology

- Ablation or freezing of skin cancers and other cutaneous disorders

Concurrence of CDRH, Office of Device Evaluation (ODE):

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K003811

Prescription Use: X
(Per 21 CFR 801.109)

Gynecology

- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

General Surgery

- Destruction of warts or lesions
- Palliation of tumors of the oral cavity, rectum and skin
- Ablation of breast fibroadenoma
- Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemanglomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, recurrent cancerous lesions

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Concurrence of CDRH, Office of Device Evaluation (ODE):

Prescription Use: X
(Per 21 CFR 801.109)